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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,154	12/10/2001	Ryusuke Nakagiri	2139.27	2545

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NEW YORK, NY 10112

EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/010,154

Applicant(s)

NAKAGIRI ET AL

Examiner

Gollamudi S. Kishore, Ph.D

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6, 16, 24, 30, 31, 37, 38, 43, 44, 49, 50 and 52-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6, 16, 24, 30-31, 37-38, 43-44, 49-50 and 52-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The RCE dated 11-18-04 is acknowledged.

Claims included in the prosecution are 6, 16, 24, 30-31, 37-38, 43-44, 49-50 and 52-58.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 6, 16, 24, 30-31, 37-38, 43-44, 49-50 and 52-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 4, line 11, applicant states that "the plant of the family saxifragaceae belongs to the genus Saxifraga". On line 18 however, applicant states "the plant of the family Saxifragaceae belongs to the genus Hydrangea". Which is the species and which is the genus? It is very confusing.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 6, 16, 24, 30-31, 37-38, 43-44, 49-50 and 52-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear from the independent claims what the final product is which is responsible for improving the liver function. Is the final product, the residue or the filtrate obtained by alcohol or water containing alcohol medium?

The newly added claims 52-58 are confusing. According to the independent claims, the filtrate is an extract of the residue obtained by extracting with alcohol or water containing alcohol. The dependent claims 52-58 recite, "the active ingredient is an extract of the filtrate". Is this extraction step in addition? If so what is the filtrate extracted with?

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 6, 16, 24, 31, 38, 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Konishi (6,541,041) as set forth in the previous action.

Applicant's arguments have been fully considered, but are not found to be

persuasive. Applicant argues that Konishi describes extracts containing soluble silicon compounds obtained by subjecting plants including Saxifrage stolonifera to extraction with water or aqueous solvent and that Konishi does not relate to a filtrate obtained by extracting that extract residue with alcohol or water containing alcohol. These arguments are not persuasive. First of all, the rejected claims are composition claims and applicant has not shown that instant extract is patentably distinct from Konishi's extract. Secondly, Konishi clearly teaches extraction using water and ethanol (col. 4, line 18 et seq.). The examiner disagrees with applicant's arguments that Konishi teaches silicon compounds; the examiner is unable to find such teachings in the reference. The examiner also points out that intended use has no significance in composition claims.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 30, 37, 43, 44, 49, 55, 56 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamahara (XP 002220391) in combination with Levinson et al (6,479,545) as set forth in the previous action.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Yamahara, and Levinson teach only alcohol extracts and not filtrates obtained by extracting with alcohol an extract residue wherein that

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extract residue is obtained by extraction with an aqueous medium. This argument is not found to be persuasive. The very fact that applicant uses the filtrate obtained by alcohol extraction indicates that whatever compounds are responsible for improving the liver function are present in the alcohol extract. That means these compounds will be present whether alcohol is used to extract from the plant itself or residue obtained by initial extraction. Applicant has not shown that the methanol (alcohol) extracts of Yamahara are different from instant extracts in terms of the compounds, which are responsible for improving the liver function. With regard to applicant's arguments that a combination of two disparate extractions results in markedly greater liver function protection or improvement compared with an extract obtained by a one-step extraction, the examiner points out that it would be obvious to one of ordinary skill in the art that a given solvent will extract only those compounds which are soluble in that solvent and therefore, alcohol would extract the same compounds whether the starting material is the plant itself or a residue obtained after initial treatment with water (water will remove those which are soluble in water. The examiner sees no unexpected results. Applicant has not isolated a specific compound from the extracts taught by the prior art to show its involvement in improving the liver function in order to claim unobvious results. The newly added claims 55, 56 and 58 are included in this rejection since these claims merely recite further extraction of the extract and the same rationale as set forth above is applicable for these claims also.

9. Claims 6, 16, 24, 31, 38, 43, 44, 52-55 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuji Rebio (XP 002220392) in combination with Konishi (6,541,041) as set forth in the previous action.


Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Rebio describes that tannins purified from Saxifragasto lonifera can be used for the treatment of hepatitis B, but teaches no method of purifying tannin. This argument is not found to be persuasive. Instant claims recite a composition for protecting liver function using Saxifragasto extracts and the prior art goes one step further in isolating specific compounds responsible for protecting the liver function and applicant has not shown any unexpected results obtained using an extract from Saxifragasto as opposed to the purified tannins obtained from Saxifragasto extracts. The examiner has already addressed applicant's arguments with regard to Konishi. The newly added claims 52-55 and 57 are included in this rejection since these claims merely recite further extraction of the extract and the same rationale as set forth above is applicable for these claims also.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK